SECTION 2: Targeted Outreach and Counseling, Testing, and Referral for High Risk Individuals

Activities included in this section are intended to help agencies target HIV counseling and testing to persons at high risk for HIV. Both traditional and rapid HIV testing procedures are included. These activities include HIV counseling and testing in traditional settings such as counseling, testing, and referral (CTR) sites and medical settings, as well as non-clinical settings such as correctional facilities, social functions, and other venues where persons at high risk congregate.

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF COUNSELING, TESTING AND REFERRAL

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF HIV COUNSELING, TESTING AND REFERRAL

CDC estimates that 850,000 to 950,000 persons in the United States are living with HIV; of those, an estimated 25% are unaware of their infection. Evidence suggests that as many as two-thirds of the estimated 40,000 new HIV infections each year occur through transmission from persons who are unaware of their HIV status. Research also demonstrates, however, that after a positive HIV test result individuals generally decrease their risk behavior.[1]

HIV Counseling, Testing, and Referral (CTR) [2,3] refers to a collection of activities designed to increase a client's knowledge of his/her HIV serostatus, encourage and support risk reduction, and to secure needed referrals for appropriate medical, prevention, and partner counseling and referral services (PCRS). CTR can be provided in a number of settings using a variety of methods, but all CTR services address 5 basic requirements:

1) Inform clients about HIV transmission routes, the HIV antibody testing process, and the meaning of a positive or a negative test result.

2) Provide client-centered counseling around issues of recognizing one's risk for HIV infection, risk-reduction, and the need for testing.

3) If appropriate, test clients using the best available method.

4) When using the rapid HIV test, all standards and procedures related to the use of the rapid test including guidelines for providing preliminary results and obtaining specimens for confirmatory testing are followed (see Procedural Guidance for Rapid Testing in Non-Clinical Settings in this document for additional information on the rapid HIV test).

5) Address needs for additional services and provide suitable referrals to meet those needs.

CTR can be delivered anonymously or confidentially, but it should be voluntary and undertaken only with informed consent. Several HIV test technologies have been approved by the Food and Drug Administration including tests of different fluids (whole blood, serum, plasma, oral fluids, and urine) and durations (e.g., rapid tests) offering flexibility in testing option to facilitate client access to and acceptability of testing.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which ~~it~~ the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. CTR has 8 core elements which include:

1) HIV CTR is a voluntary service that can only be delivered after informed consent is obtained.

2) Information and education are provided regarding:
    a. risk for transmission and how HIV can be prevented
    b. the type of HIV antibody test used
    c. the meaning of the test result including a discussion of the window period for HIV seroconversion (the time after infection, before antibodies are produced by the body in which and antibody test might be negative despite the presence of HIV)
    d. where to obtain further information, counseling, or other services (medical or mental health care)

3) Client-centered counseling is provided to address the client's readiness for testing as well as his/her personalized risk assessment, steps taken to reduce risk, risk-reduction goals, support systems, referral needs, and plans for obtaining results if necessary (if testing is provided and the agency is not using rapid testing).

4) In conjunction with the state and/or local health departments and community mental health providers, establish guidelines and define sobriety standards for counselors to use to determine when clients are not competent to provide consent. These guidelines should be unambiguous and easy to implement.

5) HIV testing is conducted using a Food and Drug Administration (FDA) approved testing technology. When rapid HIV testing is offered, please see the Procedural Guidance for Implementation of Rapid Testing in Non-Clinical Settings in this document.

6) Test results are delivered in a supportive fashion and in a way that is understandable to the client.

7) Referral needs in support of risk reduction or medical care are assessed and appropriate referrals are provided with assistance linking clients with providers. A system must be in place for emergency medical or mental health referral if needed.

8) Referrals made and completed are tracked.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These

characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. CTR has 5 key characteristics**:**

- Information giving and educational elements of testing may be provided through face-to-face contact, in small or large group settings, or using brochures, handouts, videos, tape recordings, or other non-personalized information delivery manner
- Client-centered counseling and test results should be delivered in an individual, face-to-face session. While some providers have given negative test results over the telephone when a face-to-face session is not feasible, it is recommended that positive results be given in person to ensure the client has the necessary support and completes referrals for care and prevention services.
- A variety of specimens and test types are used in conducting HIV-antibody testing depending on the setting in which it is conducted and the needs of the organization and the client
- Service referrals that match the client's self-identified priority needs are more likely to be completed, however priority should be placed on referrals for medical care and PCRS (for clients testing positive), and for prevention and support services.

Procedures describe the activities that make up the content of the service and provide direction to agencies or organizations regarding delivery of the service. Procedures for CTR follow:

HIV CTR may be anonymous (the client's name is neither known nor solicited, and is not recorded) or confidential (the client provides his/her name and may or may not provide additional contact information), and it may be provided by self-referral (the client has made the decision to seek services individually) or by referral from other related services (medical or mental health care, substance abuse treatment, homeless shelters, partner counseling and referral services). In addition, it may be accessed in a clinic or office setting, or it may be brought to less traditional venues and provided as a part of outreach, or other services (PCM, other prevention interventions). In each of the instances of testing, however, a similar set of procedures is followed. If agency is using rapid HIV testing technologies, please review the *Procedural Guidance for Implementation of Rapid Testing in Non-Clinical Settings* in this document.

Information-Giving and Education: The client is first given information about HIV and the antibody test. This information must include a discussion of the risk factors for HIV and the how HIV can be prevented, the type of test to be used, and the manner in which a specimen will be collected for testing. The timeframe for testing should be also discussed including when the results will be available (and the importance of obtaining test result), and what positive and negative test results may indicate. The client should be counseled regarding the window period for HIV seroconversion so that he/she can determine if testing is appropriate or if testing at a later time might provide more information. Finally, referral to partner counseling and referral services (PCRS) in the case of a positive result should be discussed. When all aspects of the test have been disclosed, the client is able to make an informed decision regarding whether he/she should be tested. The client should then provide consent (verbal or written, as required by state/local policy) indicating his/her willingness to be tested for the presence of the HIV antibody. If testing is anonymous, the client should be informed that providing a sample for testing implies consent.

Client-Centered Counseling: Client-centered counseling techniques are used to help the client to determine his/her readiness for testing including support systems to access while waiting for and after receiving the test results. The client's ability to cope with a positive test result should also be assessed.

If the client indicates a willingness to continue with the test, an individualized risk assessment is conducted to determine the client's risk behaviors and the relative level of risk that they entail. This information should be shared with the client to assist him/her in developing an enhanced self-perception of risk and to enable the client and the counselor to identify, acknowledge, and understand the details and context of the client's risk. Factors associated with continued risk behavior that might be important to explore include using drugs or alcohol before sexual activity, underestimating personal risk, perceiving that precautionary changes are not an accepted peer norm, perceiving limited self-efficacy for successful change efforts, receiving reinforcement for frequent unsafe practices (e.g., a negative HIV test result after risk behaviors), and perceiving that vulnerability is associated with "luck" or "fate". Keeping the focus of the assessment personal is intended to help the client identify concrete, acceptable protective measures to reduce personal HIV risk.

The counselor should acknowledge, and provide support for positive steps that the client has already made toward risk-reduction and then negotiate a concrete achievable behavior-change step that will reduce HIV risk. Counselors should focus on reducing the client's current risk and limit general education regarding HIV transmission modes and the meaning of HIV test results. Although the optimal goal is to eliminate HIV risk behaviors, small behavior changes can reduce the probability of acquiring or transmitting HIV. Behavioral risk-reduction steps should be acceptable to the client and appropriate to the client's situation. For clients with several high-risk behaviors, the counselor should help clients focus on reducing the most critical risk they are willing to commit to changing. The step should be relevant to reducing the client's own HIV risk and should be a small, explicit, and achievable goal, not a global goal. Identifying the barriers and supports to achieving a step, through interactive discussion, role-play modeling, recognizing social support or other methods will enhance the likelihood of success. In addition, the counselor should provide skill-building opportunities related to the goal including having the client demonstrate proper condom usage or paraphernalia cleaning (with feedback) or role-playing negotiation of abstinence or safer sex in a relationship. For clients with ongoing risk behaviors, referral to additional prevention and related support services is encouraged. A structured protocol outlining session goals can help keep the counselor focused on risk reduction and ensure consistent delivery from client to client. An example of a counseling protocol from the RESPECT model of HIV prevention counseling can be found at http://www.cdc.gov/hiv/projects/respect/default.htm

Conducting the Test: After counseling, referrals are provided (see below regarding making referrals) if necessary and the HIV-antibody test is conducted according to the procedures outlined by the test's manufacturer, and a follow-up appointment is scheduled if necessary or desirable. If the rapid HIV-antibody test is used a follow-up appointment may not be necessary, but for traditional HIV-antibody testing results are given at a second appointment. The counselor should schedule the appointment at the time and place that is most likely to result in the client

returning for results.

Providing Results: Results should be provided at the beginning of the results-giving session using explicit language. Counselors should never ask the client to guess the test results. Counselors should, however, clarify test results (for an explanation of test results, please refer to the *Revised Guidelines for HIV Counseling, Testing, and Referral*.[1]) and discuss implications for continued risk reduction commitment. This discussion should address personal HIV risk reduction for clients with negative test results (including reviewing progress on goals set at the previous counseling session) and additional considerations for clients with positive or indeterminate test results.

For clients with a positive test result, the counselor may need to provide psychological support and/or make a referral for additional counseling if indicated. The counselor should ensure that the client knows where and how to obtain further information and services, and referrals should be provided for medical evaluation, care, and treatment (including sexually transmitted disease (STD) screening and care and screening and vaccination or treatment for viral hepatitis, and referral for reproductive health services). The counselor should ensure that the client has accurate information about how HIV is transmitted and how transmission can be prevented. Misconceptions regarding HIV transmission risk should be elicited and addressed, and the counselor should provide prevention counseling to address strategies for prevention of other STDs or bloodborne infections.

The counselor should assess the need for, and provide or make referrals for other prevention services (individual- or group-level interventions or PCM). The client should also be counseled regarding whom to notify of his/her positive test result, and a discussion of and referral to PCRS should be provided.

Referral: Referrals for additional services may be made at any point in the CTR process. Some referrals that should be considered include:

- STD screening and care
- Viral hepatitis screening, vaccination, and treatment
- Housing
- Food
- Transportation
- Domestic violence
- Reproductive health services
- Chemical dependency prevention and treatment
- Mental health services
- Legal services
- Other support services

CTR sites should develop and maintain a referral resource guide, and nurture strong working relationships with provider agencies. Key contacts from these agencies should be identified, and formal written agreements should delineate the roles and responsibilities of each agency. Sites should review their referral agreements periodically and modify them as appropriate. If barriers

to successful referrals exist these should be addressed initially and on an ongoing basis.

When making a specific referral for a client, the counselor must consider the most appropriate service provider for the client, considering such issues as the client's culture, language, sex, sexual orientation, age, or developmental level. The counselor should work with the client to identify barriers to completing the referral and the means of addressing those barriers. Referrals are most likely to be completed if they match the client's self-identified priority needs, the client is provided with a contact at the agency to which he/she is referred, and the counselor is able to provide some personalized information about the agency including a contact name, eligibility requirements, location, hours of operation, and the telephone number. More than one referral option should be provided if possible. The referral may be also facilitated if the counselor can call the service provider with the client, however, prior to exchanging any information regarding a client, the counselor must have a signed informed consent form to share private information from the client.

All referrals should be documented, and tracked to determine if they were completed. If the client did not, barriers to completion should be addressed. If the referral was completed, satisfaction with the referral should be assessed and this information should be maintained in the referral resource guide. If services were unsatisfactory, additional referrals should be made if possible. Information obtained through follow-up of referrals can identify barriers to completing the referral, responsiveness of referral services in addressing client needs, and gaps in the referral system.

RESOURCE REQUIREMENTS

Paid or volunteer staff members implementing CTR must be trained in HIV counseling, testing, and referral. If rapid HIV testing will be used, the staff member must be trained in the delivery of rapid HIV testing and all polices, quality assurance requirements, and local and state requirements related to rapid HIV testing must be followed (see *Procedural Guidance for Implementing Rapid Testing in Non-clinical Settings* in this document). Staffing levels will vary depending on the number of tests that are required. Depending on the needs of the clients, the abilities of the counselor, and the type of test (rapid or traditional), individual counselors may provide between one and two tests per hour. Providing positive results will take additional time. Agencies should staff their programs according to the projected need for testing in their area. This information can be obtained from an appropriate needs assessment and a review of the local epidemiological profile (the HIV prevention community plan and other sources of relevant information).

RECRUITMENT

The following recruitment strategies can be used to reach clients for CTR:

- Recruit from HIV prevention counseling, prevention case management, or other agency services

- Recruit from other community based organizations that serve high-risk populations, e.g., substance abuse treatment facilities, correctional facilities, shelters.
- Send press releases and/or public service announcements to radio stations and TV stations that are targeted to specific populations at high risk for HIV
- Advertise in local newspapers (including neighborhood/gay/alternative papers, etc.)
- Post announcements on the Internet

Agencies choosing to implement Counseling, Testing and Referral services, should review the Procedural Guidance for Recruitment in order to choose a recruitment strategy that will work in the setting in which they plan to implement CTR services.

PHYSICAL SETTING CHARACTERISTICS

CTR can be implemented at any location where confidentiality of clients can be ensured (e.g., private area or room). The agency must be able to safely collect specimen samples of clients who wish to be tested according to minimal standards as outlined by the Occupational Safety and Health Administration (OSHA).

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement CTR services the following policies and procedures should be in place to protect clients, CTR providers, and the agency:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in appropriate language the agency's responsibility and the client's rights. In some states informed consent is not required to be written and can be given verbally. **Client participation must always be voluntary and documentation of this informed consent must be maintained in the agency records.**

Legal/Ethical Policies: It is important to keep in mind that the implementation of CTR services deal with the provision of services that requires specialized training and deals with private client medical information. Agencies must know their state laws regarding who may implement CTR procedures and about disclosure of a client's HIV status (whether positive or negative) to sexual partners and other third parties. Agencies are obligated to inform clients about state laws regarding the reporting of child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Safety: CTR services that are provided in non-traditional settings may pose potentially unsafe situations, e.g. the risk of transmitting blood borne pathogens. Agencies should develop and maintain written detailed guidelines for personal safety and security in non-traditional settings, for assuring minimal safety standards (including biohazard waste disposal) as outlined by the

Occupational Safety and Health Administration (OSHA) and to safeguard the security of the data collected, client confidentiality and the chain of custody for testing supplies and collected client specimens. Agencies must ensure that CTR providers are aware of and comply with safety guidelines.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality. Agencies should have written protocols on how to collect, document, analyze, and use CTR data according to State and local policies.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to clients as necessary. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services, Health Department/Community Based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct this intervention, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for counselors and clients and review of the setting should be in place when implementing CTR:

Counselor: Agencies should have a training program in place for all new employees, existing employees and volunteers that will be providing CTR services. This program should ensure that all CTR providers receive adequate training, annual training updates, continuing education and adequate supervision to implement CTR services and the rapid HIV test if appropriate. It should also ensure that CTR providers are skilled and competent in the provision of services by using observed practice of CTR sessions with feedback to counselors and of rapid HIV test procedures if needed. Agencies should have in place a mechanism to assure that all testing protocols are

followed as written. QA activities can include observation as well as role-play demonstration of skills. The review should focus on ensuring that the protocol is delivered with consistency and responsiveness to expressed client needs and should assist counselors with intervention delivery and skill development. Selected intervention record reviews should focus on assuring that consent was obtained or documented for all participants and all process and outcome measures are completed as required. For CBOs using rapid HIV test technology, please review the *Procedural Guidance for Rapid Testing in Non-Clinical Settings* in this document.

Client: Clients' satisfaction with the services and their comfort should be assessed periodically.

Setting: Supervisors should periodically review the setting to ensure that it is private and confidential and that the waiting time for a test does not create a barrier to testing.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report client level data;
- Collect and report standardized process and outcome data consistent with CDC's requirements;
- Use the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may, under certain circumstances, use a local system provided that it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
    - **II.A-** Percent of newly identified, confirmed HIV positive test results among all tests funded by CDC and reported by your organization.
    - **II.B-** Percent of newly identified, confirmed HIV positive test results returned to clients.
    - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.

KEY ARTICLES AND RESOURCES

[1]CDC. Advancing HIV prevention: New strategies for a changing epidemic. MMWR 2003; 52;3 329-332.

[2]CDC. Revised guidelines for HIV counseling, testing, and referral. MMWR 2001; 50 RR-19.

[3]Powderly WG, Mayer KH. (2003). Centers for Disease Control and Prevention revised guidelines for human immunodeficiency virus (HIV) counseling, testing, and referral: Targeting HIV specialists. Clin Infect Dis **[year?];** 37:(15), 83

CDC, Division of HIV/AIDS Prevention-Intervention, Research and Support, Capacity Building Branch, Training and Development Team; HIV Prevention Train the Trainer Course Series: Fundamentals of HIV Prevention Counseling, "Making Effective Referrals" Unit 5
Assuring the Quality of HIV Prevention Counseling: Practical Approaches for Supervisors

CDC. Revised Guidelines for HIV Counseling, Testing, and Referral.
http://www.cdc.gov/mmwr/PDF/rr/rr5019.pdf

RESPECT Counseling, Testing, and Referral Protocol.
http://www.cdc.gov/hiv/projects/respect/default.htm

Rapid Testing website. http://www.cdc.gov/hiv/rapid_testing/

U.S. Department of Health and Humans Services, OPHS Office of Minority Health. (2001). National Standards for Culturally and Linguistically Appropriate Services in Health Care.

U.S. Department of Health and Human Services. Centers for Disease Control and Prevention. (Nov 2003). Draft CDC Technical Assistance Guidelines for CBO HIV Prevention Program Performance Indicators.

U.S. Department of Labor, Occupational Safety and Health Administration. Occupational Safety and Health Standards. Toxic and Hazardous Substances. Blood borne Pathogens. Part 1910.1030, Appendix A

PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF RAPID TESTING IN NON-CLINICAL SETTINGS

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF RAPID TESTING IN NON-CLINICAL SETTINGS

Outreach efforts for HIV prevention activities provide access to hard-to-reach populations at high risk for HIV. Bringing HIV prevention counseling, testing, and referral (CTR) to these outreach sites through the use of mobile vans and HIV tests designed for oral fluid has helped to increase knowledge of serostatus among many groups.

Testing programs in non-clinical venues are more likely to reach members of some racial and ethnic minorities and persons at increased risk for HIV. Compared with persons tested at conventional testing sites, those tested at non-clinical sites were twice as likely to report high-risk heterosexual contacts and 3 to 4 times as likely to report injection drug use or male-to-male sex.[1] A California outreach program called Neighborhood Interventions Geared to High-risk Testing (NIGHT) offers street outreach, HIV counseling and testing, and referrals through the use of mobile vans. NIGHT was the source of more than 104,000 tests during 1997 and 2001. Compared with other testing sources, NIGHT reached a higher proportion of African Americans (28% versus 13%), injection drug users (23% versus 11%), stimulant drug users (45% versus 25%), and commercial sex workers (12% versus 5%).[2]

The rate of HIV-positive tests in non-clinical settings is generally high and consistently higher than at conventional testing sites.[1] In Wisconsin, persons tested in outreach were 23% more likely to test HIV-positive than those tested in clinics.[3] Of the 597 persons tested in mobile vans and street outreach in a 1999 initiative to enhance prevention efforts in African American and Latino communities in 4 U.S. cities, 8.7% were HIV-positive.[4] In South Carolina, 54% of men approached in a gay bar agreed to oral fluid testing; although 78% had been tested before, 6% were newly diagnosed with HIV.[5] In CDC's Young Men's Survey in 7 cities, a total of 3,592 15-to-22-year-old men who have sex with men approached in 194 non-clinical testing settings (public venues) consented to HIV testing. Overall prevalence was 7.2%. Although 79% of the men had been tested previously, 203 (82%) of the 249 HIV-positive men did not know that they were currently HIV-positive.[6]

Unfortunately, many persons tested in non-clinical settings do not return for their test results. CDC's national data from 2000 indicate that results from nearly half of the HIV-positive tests performed in non-clinical settings were never received. In California's NIGHT program, mobile testing clients were three times less likely to receive their test results than clients tested at conventional sites. In contrast, limited experience to date with rapid testing in outreach programs is encouraging. In a Minnesota program, an outreach worker regularly visited community-based

organizations (CBOs), homeless shelters, chemical dependency programs, and needle exchange programs to offer rapid HIV testing. When results were provided the same day, 99.9% of those tested received their HIV test results. [7]

Interviews of persons at non-clinical settings reveal features important to the success of this type of testing. For high-risk persons at a needle exchange program and gay bath houses, 36% of those who had never been tested and 28% of those who had delayed testing gave "not wanting to go to a clinic" as their reason.[8] Participants in other testing initiatives cite a desire to receive HIV results immediately and a need for testing during expanded hours as important reasons to increase alternative testing opportunities. [9]

The OraQuick Rapid HIV-1 Antibody Test, which can be suitable for use in selected non-clinical settings and can provide results in 20 minutes, offers an opportunity to take advantage of the benefits of outreach testing and ensure that tested persons receive their results. It is important to realize that positive tests from any setting must always be confirmed using a second, more specific test (e.g., the Western Blot). Therefore, until the positive result is confirmed, the result is determined to be "preliminary positive."

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which ~~it~~ the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Rapid testing in non-clinical settings has 7 core elements which include:

1) Assess the community to determine
    a. in which populations HIV is likely to be under-diagnosed (because risk is underestimated, and/or because traditional counseling, testing, and referral services are not used)
    b. where persons at risk and/or underdiagnosed can be reached.

2) The agency must have a written agreement with the state Health Department and/or a laboratory to ensure compliance with the Clinical Laboratory Improvement Amendments (CLIA) and state and local regulations and policies.

3) A clear supervisory structure should be delineated to ensure responsibility for training and guidance, oversight for testing procedures, and coordination.

4) Train or ensure training of non-clinical providers to perform rapid HIV testing including the following essential elements:
    a. Perform the test, including procedures performed before, during, and after testing
    b. Integrate rapid testing into the overall counseling and testing program
    c. Develop and implement a quality assurance (QA) program
    d. Collect and transport specimens for confirmatory testing

e. Ensure specimen integrity
f. Document and deliver confirmatory testing results to persons whose rapid test results had been preliminary positive
g. Comply with universal and biohazard safety precautions
h. Ensure confidentiality and data security
i. Ensure compliance with relevant state or local regulations

5) In conjunction with the state or local health department and community mental health providers, establish guidelines and define sobriety standards for counselors to use to determine when clients are not competent to provide consent. These guidelines should be unambiguous and easy to implement.

6) Confirmatory testing of preliminary positive tests must be assured.

7) Clients with a confirmed HIV-positive diagnosis must be provided with or referred for medical evaluation, partner counseling and referral services, and other appropriate prevention services.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. Rapid Testing in non-clinical settings has 3 key characteristics:

- Arrange appropriate referral agreements (for medical and social services) and develop strategies for follow-up.
- Obtain detailed locating information on clients whose test results are preliminary positive so that they can be contacted and encouraged to come in for care if they fail to return for their follow-up appointment. The Health Department and the testing program should specify who is responsible for follow-up if clients fail to return for confirmatory test results.
- Assemble the testing supplies for easy storage and transportation to each testing site. Individually packaged rapid test kits include all the supplies and materials necessary to facilitate single client testing in non-clinical settings.

Procedures describe the activities that make up the content of the service and provide direction to agencies or organizations regarding delivery of the service. Procedures for providing rapid HIV-testing in non-clinical settings follow:

By allowing agencies to bring testing into the community and provide test results quickly, the OraQuick Rapid HIV-1 Antibody Test can be used to reach groups in which HIV-infection has been traditionally under-diagnosed because people do not recognize that they are at risk for HIV infection, and/or they do not use traditional HIV counseling, testing, and referral services. Agencies considering the use of rapid testing in non-clinical, or outreach, settings should begin by assessing their community. Agencies should seek input from their community planning groups, other community based service providers, and representatives of their target populations

to determine the venues where persons at high risk for HIV are likely to spend time, and where rapid testing services could be delivered without an appointment, with little waiting time, and with no barriers such as transportation (see the Physical Setting Characteristics section below).

If the needs assessment indicates that rapid testing outside of a clinical setting is both appropriate and feasible, the agency must ensure an understanding of, and compliance with the Clinical Laboratory Improvement Amendments (CLIA) and all state and local regulations and policies through a written agreement with the state or local health department and/or laboratory which delineates responsibility for training and guidance, oversight for testing procedures, and coordination of services and which ensures that confirmatory testing of preliminary positive results is provided.

CDC recommends that any individual who is responsible for the delivery of the rapid test should be trained in and familiar with the fundamentals of client-centered HIV prevention counseling; performing the rapid test; providing and interpreting test results, including the meaning of negative, preliminary positive, and invalid test results; providing referrals for services (including for social services as well as medical care), and reporting of positive test results to the state or local health department.

Delivery of the rapid test in non-clinical settings differs from standard CTR, however, in that testing materials must be carried to the testing site. Individually packaged rapid test kits include all the supplies and materials necessary to facilitate single client testing in non-clinical settings; agencies must devise a means for easy storage and transport of testing materials. In addition, because the test is not conducted in a clinic setting, specimens collected for confirmatory testing must be transported to a laboratory for analysis. Specimen handling and tracking procedures must be devised to assure the safety and integrity of the specimen, and to comply with Occupational Safety and Health Administration (OSHA) regulations for handling of infectious waste. An exposure control plan must be devised for potential occupational exposures.

Because preliminary positive results must be confirmed with laboratory testing, detailed locating information must be obtained for all persons with a preliminary positive test so that they may be contacted to come in for care should they fail to return for their follow-up appointment. The state or local health department and CBO must specify who is responsible to follow-up in the event that a client fails to return for confirmatory test results. In some states, preliminary positive results cannot be given to clients. In these cases, consideration should be given, where appropriate, to eliminating such barriers to rapid testing.

Training is available from CDC which addresses the essential elements of HIV rapid test delivery. Agencies should also frequently review the package insert for the rapid HIV test to note any recommended changes related to test delivery and use. Agencies who choose to implement rapid testing in non-clinical settings should determine the most appropriate way to integrate this service into their existing CTR services.

RESOURCE REQUIREMENTS

Staff members implementing rapid testing in non-clinical settings must be trained in HIV counseling, testing, and referral and in the delivery of rapid HIV testing. Training should include all topics noted in the Quality Assurance section below. Staffing levels will vary depending on the number of tests that are required. Depending on the needs of the clients and the abilities of the counselor, individual counselors may provide between one and three tests per hour. Providing positive results will take additional time. Agencies should staff their programs according to the projected need for rapid testing in an area. This information can be obtained from an appropriate needs assessment and a review of the local epidemiological profile (the HIV prevention community plan and other sources of relevant information).

RECRUITMENT

Agencies choosing to implement rapid testing in non-clinical settings, should review the Procedural Guidance for Recruitment in order to choose a recruitment strategy that will work in the setting in which they plan to implement these services.

PHYSICAL SETTING CHARACTERISTICS

Rapid testing can be implemented at any location where confidentiality of clients can be assured (e.g., private area or room) and where a specimen sample can be collected according to minimal standards as outlined by OSHA. In addition, the setting must have a flat surface, acceptable lighting, and temperature control (59-80°F), and the priority population must remain at the venue long enough to receive counseling, testing, and results.

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement rapid testing in non-clinical settings the following policies and procedures should be in place to protect clients, the agency, and the test provider:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in appropriate language the agency's responsibility and the client's rights. In some states informed consent is not required to be written and can be given verbally. Client participation must always be voluntary and documentation of this informed consent must be maintained in the agency records. Clients offered HIV testing at non-clinical venues may be under the influence of alcohol or drugs or have chronic mental health conditions, any of which may interfere with their ability to provide informed consent for voluntary HIV testing, or to understand test results. Agencies should work with their state or local health department and with community mental health providers to establish guidelines and define sobriety standards for counselors to use to determine when clients are not competent to provide consent. These guidelines should be unambiguous and easy to implement. Because regulations vary by state, agencies should be familiar with informed consent requirements in their state.

Legal/Ethical Policies: It is important to keep in mind that the implementation of rapid testing in non-clinical settings requires specialized training and deals with private client medical

information. Agencies must know their state laws regarding who may implement CTR and rapid testing procedures and about disclosure of a client's HIV status (whether positive or negative) to sexual partners and other third parties. Additionally, some state laws prohibit the disclosure of preliminary positive test results. Agencies must also know, and adhere to all CLIA regulations for testing, documentation, and use of logs relating to test implementation. Finally, agencies are obligated to inform clients about state laws regarding the reporting of child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Safety: CTR and rapid testing services that are provided in non-traditional settings may pose potentially unsafe situations, e.g. the risk of transmitting blood borne pathogens. Agencies should develop and maintain written detailed guidelines for personal safety and security in non-traditional settings, for assuring minimal safety standards regarding specimen collection as outlined OSHA, and to safeguard the security of the data collected, client confidentiality and the chain of custody for testing supplies and collected client specimens. Agreements with law enforcement, owners of social venues such as bathhouses or sex clubs, neighborhood associations, and other key partners should be established before testing activities begin.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to clients as necessary. After preliminary positive rapid test results have been provided, follow-up procedures should be in place to ensure that the client returns for confirmatory test results. A follow up visit must be scheduled at the referral medical center where confirmatory test results and referrals for care can be provided. HIV counselors from the non-clinical site may accompany clients to the medical center to provide support and ensure continuity of care. Providers must know about referral sources for prevention interventions/counseling (Partner Counseling and Referral Services,

Health Department/Community Based Organization programs for prevention interventions with PLWH) if consumers need additional assistance in decreasing risk behavior.

QUALITY ASSURANCE

Quality assurance activities for counselors and clients and review of the setting should be in place when implementing rapid testing in non-clinical settings:

Counselor: Agencies should have a training program in place for all new and existing employees providing rapid testing services. This program should ensure that all providers receive adequate training, annual training updates, continuing education, and appropriate supervision to implement rapid testing services including training on:

- Client-centered HIV prevention counseling
- Providing information to persons being tested before testing
- HIV transmission and prevention of HIV and other STDs
- The natural history of HIV
- Partner counseling and referral services
- Prevention case management
- Prevention and support services in the area
- Using gloves for personal protection
- Safe disposal of biohazardous waste, including used lancets
- Maintaining sufficient supplies and unexpired test and control kits (including proper storage and performance checks for new test kit lots and shipments with external controls
- Maintaining and documenting the temperature of the room and refrigerator where the tests and controls are stored and testing is performed
- Performing quality control testing and taking action (e.g., contacting the supervisor or manufacturer) if controls do not work
- Collecting specimens
- Performing the steps in the test procedure
- Reporting results
- Referring specimens or persons being tested for confirmatory testing and manage confirmatory test results
- Recording test and quality control results
- Conducting external quality assessment (please refer to the rapid HIV test website in the resources section)
- Reviewing records and storing and destroying them when they are outdated (how long test result records are kept as part of a medical record may be subject to State or other requirements)
- Troubleshooting and taking corrective action when things go wrong

The training should ensure that providers are skilled and competent in the provision of services by using observed practice of counseling skills integrating the rapid HIV test and of all steps of the rapid test. QA activities can include direct observation of sessions as well as role-play

demonstration of skills. The review should focus on ensuring that the protocol is delivered with consistency and responsiveness to expressed client needs and should assist counselors with intervention delivery and skill development. Control kits, available from OraSure Technologies, should be used to ensure reliability and validity of the test process and materials. CDC also offers the *Model Performance Evaluation Program* to ensure accurate testing.

Selected intervention record reviews should focus on assuring that consent was obtained or documented for all participants and all process and outcome measures are completed as required.

Client: Clients' satisfaction with the services and their comfort should be assessed periodically. Process monitoring systems should also track the number referrals made and completed as well as response to the service.

Setting: Supervisors should periodically review the settings to ensure that they are private and confidential, that the requirements of the test are met, and that the waiting time for a test does not create a barrier to testing.

MONITORING AND EVALUATION

Evaluation and monitoring intervention activities include the following:

- Collect and report client level data;
- Collect and report standardized process and outcome data consistent with CDC's requirements;
- Use the CDC developed PEMS (Program Evaluation Monitoring System) to report data electronically. Organizations may, under certain circumstances, use a local system provided that it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality;
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
    - **I.A-** The mean number of outreach contacts required to get one person with unknown or negative serostatus to access counseling and testing.
    - **II.A-** Percent of newly identified, confirmed HIV positive test results among all tests funded by CDC and reported by your organization.
    - **II.B-** Percent of newly identified, confirmed HIV positive test results returned to clients.
    - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.
    - **V.A-** The mean number of outreach contacts required to get a person (living with HIV, their sex partners and injection drug-using contacts or at very high risk for HIV infection) to access referrals made under this program announcement.

KEY ARTICLES AND RESOURCES

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CDC Model Performance Evaluation Program for Rapid HIV Testing: http://www.phppo.cdc/mpep/enrollment.asp

CDC Revised Guidelines for HIV Counseling, Testing, and Referral. http://www.cdc.gov/mmwr/PDF/rr/rr5019.pdf

CDC Technical Assistance Guidelines for CDC's HIV Prevention Program Performance Indicators. http://www.cdc.gov/hiv/dhap

CLIA application and requirements: www.cms.hhs.gov/clia

NASTAD Primer on implementing rapid HIV testing:
http://www.nastad.org/PDF/RAPIDIPRIMER.PDF

Occupational Safety and Health Administration: www.osha.gov

Product information, OraQuick Rapid HIV-1 Antibody Test: http://www.orasure.com/products/

Quality Assurance Guidelines for Testing Using the OraQuick Rapid HIV-1 Antibody Test:
http://www.cdc.gov/hiv/rapid_testing/materials/QA_Guidlines_OraQuick.pdf

Rapid HIV Testing: www.cdc.gov/hiv/rapid_testing

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PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF ROUTINE TESTING OF INMATES IN CORRECTIONAL FACILITIES

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF ROUTINE TESTING OF INMATES IN CORRECTIONAL FACILITIES

In the United States, approximately 2 million people are currently incarcerated.[1] An additional 4 million individuals are on parole or probation.[2] Men represent the overwhelming majority of the incarcerated population (92%); however, the proportion of women has been steadily increasing in recent years.[2] Minority populations are disproportionately represented among people incarcerated, with recent estimates indicating that 12% of African-American males and 4% of Hispanic males in their twenties and early thirties are incarcerated.[2]

Prisons generally house individuals with sentences of 1 year or longer,[3] and there are currently 1.3 million inmates housed in state and federal prisons.[1] Jails currently house roughly 600,000 inmates.[2] Jails are operated by a city or county and house people awaiting hearings, trials, transfer to prison, or misdemeanor convictions. People detained in jails usually serve less than 1 year. The majority serve less than two weeks.[3] Most inmates are eventually released, but many are re-incarcerated within six months.[4] This results in 7.5 million people released annually.[5]

Many individuals entering correctional facilities have a history of high-risk sexual behaviors, substance abuse, or both. As a result, high rates of HIV and sexually transmitted diseases (STDs) have been documented among persons entering the correctional system.[5] In 1999, there were more than 25,000 (2.0%) federal and state prison inmates, and more than 8,600 jail inmates (1.7%) known to be HIV-positive.[6] In addition, the prevalence of AIDS among prison populations is 5 times higher than that in the general U.S. population (0.60% versus 0.12%).[6] Recent estimates suggest that nearly 25% of people living with HIV pass through the correctional system.[7] Currently, less than half of the prison systems and few jails routinely provide HIV testing on entry.[8] Therefore, many individuals who may be infected are not routinely offered HIV testing. Providing routine HIV prevention counseling and testing within the standard medical intake evaluation for all inmates can identify HIV infection among people who are either unaware of their status, or who have tested negative with a previous test and can confirm the status of inmates who report that they are HIV-positive. Routine HIV testing can either be in the form of standard enzyme immunoassay (EIA) and Western Blot testing or rapid HIV testing with appropriate confirmation testing. Health departments or agencies approved to provide partner counseling and referral services (PCRS) should initiate this service for contacts of these HIV infected persons.

Persons incarcerated for less than 30 days may not receive traditional HIV counseling, testing, and referral (CTR), and, if they do, they are likely to be released before their test results are available. Use of rapid HIV testing could help ensure this population receives their test results. The RESPECT 2 study showed that HIV CTR that used a rapid HIV-screening test was as effective as traditional HIV CTR.[9]

Routinely providing rapid HIV CTR services for persons incarcerated for less than 30 days can greatly increase the proportion of persons tested and notified of their test results prior to release so that PCRS, prevention, and care services can be secured both within the corrections system and after release. CBOs must collaborate with the state or local health department, state and local justice and correctional departments, and officials for the individual correctional facility to address the HIV prevention needs of their inmates. If rapid testing is implemented in the correctional setting, please see the *Procedural Guidance for Implementation of Rapid Testing in Non-Clinical Settings* in this document for further guidance.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which ~~it~~ the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Routine testing of inmates in correctional facilities involves 8 core elements which include:

1) All rules and regulations of the correctional facility must be adhered to closely to assure the safety of CBO employees, inmates, and facility staff.

2) HIV counseling and testing is routinely offered to all inmates with informed consent.

3) All CTR services are provided consistent with CDC's Revised Guidelines for HIV Counseling, Testing, and Referral.

4) When using the rapid HIV test, all standards and procedures related to the use of the rapid test including guidelines for providing preliminary results and obtaining specimens for confirmatory testing are followed (see Procedural Guidance for Rapid Testing in Non-Clinical Settings in this document for additional information on the rapid HIV test).

5) All tested inmates are notified confidentially, and in person of their HIV test result (whether HIV positive or HIV negative).

6) Persons infected with HIV are referred to partner counseling and referral services, medical care and treatment, and prevention services in the correctional facility, in the community, or both.

7) HIV-negative persons at high risk are referred to prevention services in the facility, in the community, or both.

8) For infected persons or HIV-negative persons at high risk being released from the correctional facility, referral and linkage to care, treatment, and prevention services in the community is essential.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. Routine testing of inmates in correctional facilities has 6 key characteristics:

- Develop an information sheet with all relevant information regarding HIV prevention counseling, testing, and referral services to be distributed at inmate intake appointments.
- Establish a system to document consent for testing and test results, and to track specimens sent for confirmatory testing.
- Develop a system to document and track refusal of HIV testing.
- Testing of inmates may occur before, during, or shortly after the medical evaluation at intake into the correction facility.
- Collaborate with the correctional facility to devise a strategy for reporting positive results to the state Health Department.
- Key contacts should be identified within the CBO and at the correctional facility to provide accountability and continuity in the collaboration.

Procedures describe the activities that make up the content of the service and provide direction to agencies or organizations regarding delivery of the service. Procedures for routine testing of inmates in correctional facilities follow:

CBOs should initiate discussions with correctional systems that do not routinely offer HIV testing to inmates during the intake medical evaluation to determine their willingness to implement routine testing. Additionally, CBOs should assess the inclusion of rapid HIV testing in facilities implementing routine testing but not yet incorporating this new technology into their systems. CBOs must collaborate with the state or local health department, state and local justice and correctional departments, and officials for the individual correctional facility (including correctional officers and medical staff) to develop policies and procedures that promote successful training for CBO and correctional staff, and implementation of routine HIV screening and prevention services in correctional facilities and in the community. The CBO should work with facility officials to promote the importance of routine testing, and to address policies related to confidentiality and data security, documenting test results and refusals of testing, and providing inmates confidential notification of their HIV test results. The regulations of correctional facilities are designed for the protection of inmates, staff, and visitors to the facility; it is essential that agencies who wish to partner with a jail or prison understand and follow all rules of the facility.

If the facility does not already have an information sheet that has been approved by the Health Department or Department of Corrections, the CBO should collaborate with medical personnel at the jail or prison to design one that can be given to all inmates prior to their intake medical appointment. The sheet should describe the risk factors for transmitting or acquiring HIV, features of the HIV antibody test and possible results, and HIV prevention, support, and care services available within and outside of the facility. It should also advise the inmate that HIV prevention counseling, testing, and referral is provided as a routine part of the intake medical evaluation. Informed consent for the HIV test should be obtained in a manner consistent with state and facility policy. The information sheet can be used as a stimulus for the care provider to discuss HIV risk with the inmate, and to refer him or her to the CBO representative on site for CTR services.

Depending on the inmate's projected length of incarceration, a CBO representative may choose to use either standard HIV testing with an EIA test followed by a Western Blot if indicated, or rapid HIV testing with Western Blot confirmatory testing for preliminary positive diagnoses. Regardless of which strategy is used, testing must follow CDC's Revised Guidelines for HIV Counseling, Testing, and Referral and anyone providing this service should be certified in HIV prevention counseling, testing, and referral. In addition, if the rapid test is used, the CBO representative should have completed training in proper use of the test.

The CBO should work with correctional officials to identify HIV-related services within the facility and in the community. The CBO and correctional officials should work together to refer all persons with a positive test and HIV-negative persons at high risk for infection to appropriate care, treatment, and/or prevention services. The services to which the inmate is referred will be determined by his or her needs and the length of the inmate's incarceration. When possible, the initial care appointment should occur while the inmate is in the correctional facility. Inmates who test positive should be offered and encouraged to participate in partner counseling and referral services (PCRS) either by referral to the local or state health department, or by the CBO if appropriate. Other services, including discharge planning should be available either from the correctional facility, the CBO, or by referral. Relationships between the CBO, the correctional facility, state and/or local health departments and other service providers within, and outside of the facility should be formally documented and the CBO and correctional facility should designate key contacts to provide accountability and continuity in the collaboration and referral process.

RESOURCE REQUIREMENTS

Paid or volunteer staff members implementing routine testing of inmates in correctional facilities must be certified in HIV counseling, testing, and referral. If rapid HIV testing will be used, the staff member must be trained in the delivery of rapid HIV testing. Staffing levels will vary depending on the number of tests that are required. Depending on the needs of the clients, the abilities of the counselor, and the type of test (rapid or traditional), individual counselors may provide between one and three tests per hour. Providing positive results will take additional time. Agencies should staff their programs according to the projected need for testing at the

correctional facility. This information can be obtained by reviewing the facility's medical procedures, and intake process.

RECRUITMENT

Agencies implementing routine testing of inmates in correctional facilities should work with medical providers at the facility to encourage the promotion of testing during the intake medical appointment. Information flyers distributed during the intake process can facilitate discussions about HIV risk and testing by providers and can serve as a reminder for the provider to refer inmates for CTR. Agencies who choose to partner with correctional facilities to provide this service should document this relationship with a memorandum of understanding that delineates the roles and responsibilities of each partner.

PHYSICAL SETTING CHARACTERISTICS

Routine testing of inmates in correctional facilities can be implemented at any location where confidentiality of clients can be assured (e.g., private area or room) and where a specimen sample can be collected according to minimal standards as outlined by OSHA. Additionally, for rapid testing, the setting must have a flat surface, acceptable lighting, and temperature control (59-80°F).

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement routine testing of inmates in correctional facilities, the following policies and procedures should be in place to protect inmates, the correctional facility and staff, the CBO, and the test provider:

Informed Consent: Agencies must have a consent form which carefully and clearly explains in appropriate language the agency's responsibility and the client's rights. In some states informed consent can be given either verbally or in written form. Inmate participation must always be voluntary and documentation of this informed consent must be maintained in the agency records and in the inmate's medical record if appropriate. Regulations vary by state; therefore, agencies should be familiar with informed consent requirements in their state.

Legal/Ethical Policies: It is important to keep in mind that the routine testing of inmates in correctional facilities requires specialized training and deals with private inmate medical information. Agencies must know their state laws and prison policies regarding who may implement CTR and rapid testing procedures and about disclosure of a client's HIV status (whether positive or negative) to sexual partners, correctional officers, and other third parties. Additionally, some state laws prohibit the disclosure of preliminary positive test results. Agencies must also know, and adhere to all CLIA regulations for testing, documentation, and use of logs relating to test implementation. Finally, agencies are obligated to inform clients about state laws regarding the reporting of child abuse, sexual abuse of minors, elder abuse, or imminent danger or harm to a specific person.

Facility Regulations: Regulations of correctional facilities are designed for the protection of inmates, staff, and visitors to the facility. It is essential that agencies who wish to partner with a jail or prison understand and follow all rules of the facility.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained. If the referral is within the correctional facility, rules regarding communication between departments must be followed.

Safety: CTR and rapid testing services that are provided in correctional facilities may pose potentially unsafe situations, e.g. the risk of transmitting blood borne pathogens, or concerns about personal safety. Agencies should collaborate with corrections officials to develop and maintain written detailed guidelines for personal safety and security in correctional facilities, for assuring minimal safety standards regarding specimen collection as outlined by OSHA, and to safeguard the security of the data collected, client confidentiality and the chain of custody for testing supplies and collected client specimens.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to clients as necessary. HIV testing providers must know about and have linkage relationships with referral sources for care and prevention interventions/counseling (Partner Counseling and Referral Services, Health Department/Community Based Organization programs for prevention interventions with PLWH) if inmates need additional assistance in decreasing risk behavior.

Volunteers: If the agency is using volunteers to assist in or conduct CTR services, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for counselors and clients and review of the setting should be in place when implementing routine testing of inmates in correctional facilities:

Counselor: Agencies should have a training program in place for all new employees, existing employees and volunteers that will be providing CTR services. This program should ensure that all CTR providers receive adequate training, annual training updates, continuing education and adequate supervision to implement CTR services and the rapid HIV test if appropriate. It should also ensure that CTR providers are skilled and competent in the provision of services by using observed practice of CTR sessions with feedback to counselors and of rapid HIV test procedures if needed. Agencies should have in place a mechanism to assure that all testing protocols are followed as written. QA activities can include observation of sessions as well as role-play demonstration of skills. The review should focus on ensuring that the protocol is delivered with consistency and responsiveness to expressed client needs and should assist counselors with intervention delivery and skill development. Selected intervention record reviews should focus on assuring that consent was obtained or documented for all participants and all process and outcome measures are completed as required. For CBOs using rapid HIV test technology, please review the *Procedural Guidance for Rapid Testing in Non-Clinical Settings* in this document.

Selected intervention record reviews should focus on assuring that consent was obtained or documented for all participants and all process and outcome measures are completed as required.

Client: Inmates' satisfaction with the services and their comfort should be assessed periodically. Process monitoring systems should also track the number of referrals made, the number completed, and response to the service. Satisfaction with services may differ if obtained inside the correctional facility compared with services after discharge. Both should be assessed.

Facility: Supervisors should periodically review the testing facility to ensure that a private and confidential setting is available for testing, and that the waiting time for a test does not create a barrier to testing. Feedback should be solicited from correctional officers to ensure that test providers are adhering to the rules and regulations of the facility.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report date electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.

- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.
- Collect and report data on the following indicators:
    - **II.A-** Percent of newly identified, confirmed HIV positive test results among all tests funded by CDC and reported by your organization.
    - **II.B-** Percent of newly identified, confirmed HIV positive test results returned to clients.
    - **IV.A-** Proportion of client records with the CDC-required demographic and behavioral risk information.

KEY ARTICLES AND RESOURCES

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Bureau of Justice Statistics: http://www.ojp.usdoj.gov/bjs/

CDC. Revised Guidelines for HIV Counseling, Testing, and Referral. http://www.cdc.gov/mmwr/PDF/rr/rr5019.pdf

CLIA application and requirements: www.cms.hhs.gov/clia
NASTAD Primer on implementing rapid HIV testing: http://www.nastad.org/PDF/RAPIDIPRIMER.PDF

National Commission on Correctional Health Care: http://www.ncchc.org

Occupational Safety and Health Administration: www.osha.gov

Product information, OraQuick Rapid HIV-1 Antibody Test: http://www.orasure.com/products/

Public Health and Corrections Collaboration: http://www.ncjrs.org/pdffiles/169590.pdf

Rapid testing: http://www.cdc.gov/hiv/rapid_testing/

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PROCEDURAL GUIDANCE FOR IMPLEMENTATION OF UNIVERSAL HIV TESTING OF PREGNANT WOMEN

CBO PROGRAM ANNOUNCEMENT RFP 04064
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DESCRIPTION OF UNIVERSAL TESTING OF PREGNANT WOMEN

Since the first pediatric case of HIV infection was documented in 1984, tremendous medical and public health achievements have been made in preventing mother-to-child transmission of HIV. A key step toward ensuring that the perinatal HIV interventions offered are effective is to make sure that care providers know the HIV status of the pregnant women in their care. When a woman is identified as HIV infected during pregnancy, antiretroviral and obstetrical interventions can reduce the risk of having an infected baby to ≤2%. When preventive anti-retroviral treatment is not initiated until labor or birth of the newborn, the risk for transmission is 9% to 13%.[1-3] Without intervention, the risk for transmission is approximately 25% in the United States.[4]

Maximal reduction of perinatal HIV transmission in the United States depends on ensuring:

- Pregnant women receive prenatal care
- Routine HIV screening of all pregnant women
- Recommended antiretroviral regimens are used during pregnancy and labor and delivery, and after birth for HIV-infected women and their infants, as well as obstetrical interventions for women during labor and delivery
- Routine screening of women during labor and delivery or of the newborn when the mother's HIV status has not been determined previously[5]

Approximately 6,000 to 7,000 HIV-infected women gave birth in the United States in 2000, resulting in an estimated 280 to 370 HIV-infected infants. In about 40% of the perinatal transmissions, health care providers were unaware of the mother's HIV status before delivery. Additionally, in the November 15, 2002, issue of the *Morbidity and Mortality Weekly Report*, CDC published information on the most recently available prenatal HIV testing rates for the United States and Canada.[6] The report includes a comparison of the HIV prenatal testing rates associated with different testing approaches. In *opt-out*, pregnant women are notified that an HIV test will be included in the standard battery of prenatal tests and procedures and that they may refuse testing. In the more commonly used *opt-in* approach, pregnant women are given pretest counseling and must specifically consent, usually in writing, to an HIV test.

Among states using the opt-in approach and in which data were collected from medical records during 1998-1999, testing rates ranged from 25% to 69%. Population-based data from Canada showed testing rates in three opt-in provinces of 54% to 83%. In contrast, medical record data

from Tennessee, which uses the opt-out approach, revealed a testing rate of 85%. Data from Canadian provinces using opt-out approaches showed a 98% testing rate in Alberta and a 94% testing rate in Newfoundland and Labrador. At the University of Alabama's 8 prenatal clinics, HIV testing rates rose from 75% to 88% after the opt-out approach was implemented.[7]

CBOs should consider partnering with medical providers who serve women to provide referral services to ensure that the HIV prevention and service needs of both HIV-positive and high risk HIV-negative women and their children are met.

CORE ELEMENTS, KEY CHARACTERISTICS, AND PROCEDURES

Core Elements are those components that are critical features of an intervention's intent and design and that are thought to be responsible for its effectiveness and that consequently must be maintained without alteration to ensure program effectiveness. Core elements are derived from the behavioral theory upon which ~~it~~ the intervention is based. They are essential to the implementation of the program and cannot be ignored, added to, or changed. Achieving universal HIV testing of pregnant women involves 6 core elements which include:

1) Universal routine prenatal HIV testing in order to minimize perinatal HIV transmission in the United States.

2) Routine rapid HIV testing during labor and delivery for women whose HIV status is still unknown.

3) Rapid HIV testing post partum for women of unknown HIV status or their neonates, when rapid testing at labor and delivery is not possible or has been previously refused (some states mandate newborn screening in these circumstances).

4) Confirmatory testing for all preliminary positive rapid HIV test results.

5) When using the rapid HIV test, all standards and procedures related to the use of the rapid test including guidelines for providing preliminary results and obtaining specimens for confirmatory testing are followed (see Procedural Guidance for Rapid Testing in Non-Clinical Settings in this document for additional information on the rapid HIV test).

6) For pregnant women who test positive for HIV, facilitate access to appropriate obstetric, medical and social services for prevention, care, and treatment and follow up for her infant.

Key Characteristics are crucial activities and delivery methods for conducting an intervention, which may be tailored for different agencies and at-risk populations. These characteristics, however, can be adapted or tailored to meet the needs of the target population and ensure cultural appropriateness of the strategy. Universal HIV testing of pregnant women has 6 key characteristics:

- Develop an information sheet with all relevant information regarding HIV prevention counseling, testing, and referral services to be distributed at gynecological appointments and/or during labor.
- Testing is offered on an opt-out basis
- Rescreen all women in high prevalence health care facilities (> 0.5% prevalence among pregnant women) or, in low prevalence facilities, at high risk for HIV infection during the third trimester of pregnancy, or during labor and delivery
- Establish a system to document test results and to track specimens sent for confirmatory testing.
- Develop a system to document and track refusal of HIV testing.
- Work with care provider partners to provide information about the expected public health benefits of the opt-out approach to local representatives of national health care provider organizations, community groups that focus on maternal and child health issues, and state and local government officials

Procedures describe the activities that make up the content of the service and provide direction to agencies or organizations regarding delivery of the service. Procedures achieving universal HIV testing of pregnant women follow:

CBOs should initiate discussions with care providers serving pregnant women about the benefits of routine testing for HIV and of partnering to address routine testing of their patients, the ability of the CBO to provide client-centered counseling without disrupting the flow of the clinic, and ready access to services and referrals for women who test positive. For providers who choose to partner with the CBO, the CBO should work with the state or local health department and the AIDS Education and Training Centers (AETCs) of the Health Resources and Services Administration (HRSA) to facilitate the training of providers to ensure use of the opt-out approach, including documenting HIV test results in a woman's medical chart (if confidential testing is chosen) or the refusal of testing.

In collaboration with medical provider, CBOs should design an information sheet to be given to all untested pregnant women during their medical appointments (informational videos may also be used). The information should describe the risk factors for transmitting or acquiring HIV, features of the HIV antibody test and possible results, the benefits to mother and child of knowledge and treatment of HIV, and HIV prevention, support, and care services available within the community. It should also advise the patient that HIV prevention counseling, testing, and referral is provided as a routine part of the prenatal care, and that patients have the right to refuse the test. This information sheet can be used as a stimulus for the care provider to discuss HIV risk with the woman, and/or to refer her to the CBO representative on site for CTR services. The HIV antibody test may be included in a standard battery of evaluative laboratory tests used. While informed consent is required for HIV testing, if the provider has informed the patient that the test is included in the standard battery and that she can refuse testing, consent for the battery of tests is sufficient. HIV test results or the refusal to be tested should be documented in the woman's medical chart. Fact sheets on HIV testing for providers, an information sheet on HIV and other prenatal tests for women, and forms for documenting HIV test results or refusal are being developed by the American College of Obstetricians and Gynecologists. Working with

ACOG and other partners, CDC has developed a model protocol for implementing rapid HIV testing in labor and delivery settings.

For women attending health care facilities with high HIV prevalence (>0.5%), or, in low prevalence facilities, who are at high risk for HIV infection (e.g., women with HIV-positive partners) testing should be offered a second time if the test was initially refused or if the initial results were negative.

If the woman's HIV status is unknown at the time of labor and delivery, rapid HIV testing should be offered. Again, the patient should be advised of the risk factors for transmitting or acquiring HIV, features of the HIV antibody test and possible results, the benefits to mother and child of knowledge and treatment of HIV, and HIV prevention, support, and care services available within the community. If the rapid HIV test is used to screen for HIV infection all procedures for implementation of the rapid test should be followed (see Procedural Guidance for Rapid Testing in Non-clinical settings for quality assurance related to the rapid HIV test).

Women who test positive at any time during pregnancy or labor and delivery should be informed that medications can be given to her and to her newborn to reduce the chance that the baby will become HIV infected. Women whose test results with the rapid HIV test during labor and delivery are preliminary positive should immediately be offered medication for her and her newborn to reduce the chance that the baby will become HIV infected. Preliminary positive results should be confirmed with a Western Blot confirmatory test.

If the mother's HIV status remains unknown after delivery, rapid HIV testing should be offered for the mother, the infant, or both as soon as possible. Some states mandate newborn screening in this circumstance. CBOs should be aware of their individual state laws.

RESOURCE REQUIREMENTS

Paid or volunteer CBO staff members implementing universal testing of pregnant women must be certified in HIV counseling, testing, and referral. If rapid HIV testing will be used, the staff member must be trained in the delivery of rapid HIV testing. Staffing levels will vary depending on the number of tests that are required. The number of tests completed per hour depends on the needs of the clients, the abilities of the counselor, and the test used (rapid or traditional). Agencies should staff their programs according to the projected need for testing at partner clinics.

RECRUITMENT

Agencies implementing universal testing of pregnant women should work with medical providers at the partner clinics to encourage the promotion of testing during prenatal care visits, during labor and delivery, or in the postpartum period. Information flyers or videos to be used during the prenatal visits can facilitate discussions about HIV risk and testing by providers and can serve as a reminder for the provider to provide testing, or refer for CTR. Agencies who

choose to partner with medical providers to offer this service should document this relationship with a memorandum of understanding that delineates the roles and responsibilities of each partner.

PHYSICAL SETTING CHARACTERISTICS

Universal testing of pregnant women can be implemented at any location where confidentiality of clients can be assured (e.g., private area or room) and where a specimen sample can be collected according to minimal standards as outlined by OSHA. Additionally, for rapid testing, the setting must have a flat surface, acceptable lighting, and temperature control (59-80°F).

NECESSARY POLICIES AND STANDARDS

Before an agency attempts to implement routine universal testing of pregnant women, the following policies and procedures should be in place:

Informed Consent: Women should be told that HIV testing will be included in the standard batter y of prenatal tests and procedures and that she has the right to refuse testing. This information may be included in a consent form that women sign for all prenatal care and services. Specific procedures regarding consent will depend on state and local laws, regulations, and policies. Refusal to be tested should be documented in the woman's medical chart.

Legal/Ethical Policies: It is important to keep in mind that the universal testing of pregnant women requires specialized training and deals with private medical information. Agencies must know their state laws regarding who may implement CTR and rapid testing procedures and about disclosure of a client's HIV status (whether positive or negative) to sexual partners, and other third parties. Additionally, some state laws prohibit the disclosure of preliminary positive test results. Agencies must also know, and adhere to all CLIA regulations for testing, documentation, and use of logs relating to test implementation. Some states require that neonates be screened for HIV if the mother's HIV status is unknown. Agencies and their medical provider partners should be familiar with state laws regarding this requirement. Finally, agencies are obligated to inform clients about state laws regarding the reporting of child abuse, sexual abuse of minors, and elder abuse.

Confidentiality: A system must be in place to ensure that confidentiality is maintained for all participants in the program. Before sharing any information with another agency to which a client is referred, signed informed consent from a client or his/her legal guardian must be obtained.

Safety: CTR and rapid testing services may pose potentially unsafe situations, e.g. the risk of transmitting blood borne pathogens. Agencies should develop and maintain written detailed guidelines for assuring minimal safety standards regarding specimen collection as outlined OSHA, and to safeguard the security of the data collected, client confidentiality and the chain of custody for testing supplies and collected client specimens.

Data Security: Collect and report data consistent with CDC requirements to ensure data security and client confidentiality.

Cultural Competence: Agencies must strive to offer culturally competent service by being aware of the demographic, cultural, and epidemiological profile of their communities. Agencies should hire, promote, and train staff across all disciplines to be representative of and sensitive to these cultures. In addition, materials and services must be offered in the preferred language of clients/consumers where possible, or translation should be available if appropriate. Finally, agencies should facilitate community and client/consumer involvement in designing and implementing prevention services to ensure that important cultural issues are incorporated. The Office of Minority Health of the Department of Health and Human Services has published the *National Standards for Culturally and Linguistically Appropriate Services in Health Care* which should be used as a guide for ensuring cultural competency in programs and services. Please see the Cultural Competence section in the introduction of this document (page 9) for standards for developing culturally and linguistically competent programs and services.

Referrals: Agencies must be prepared to supply appropriate referrals to clients as necessary. Providers must know about and have linkage relationships with referral sources for HIV and ongoing gynecological care as well as prevention interventions/counseling (Partner Counseling and Referral Services, Health Department/Community Based Organization programs for prevention interventions with PLWH) if clients need additional assistance in decreasing risk behavior. In addition, agencies must provide necessary referrals for infants exposed to HIV.

Volunteers: If the agency is using volunteers to assist in or conduct CTR services, then the agency should know and disclose how their liability insurance and worker's compensation applies to volunteers. Agencies must ensure that volunteers also receive the same training and are held to the same performance standards as employees. Agencies must also ensure that volunteers sign and adhere to a confidentiality statement. All training should be documented.

QUALITY ASSURANCE

Quality assurance activities for counselors and clients and review of the setting should be in place when implementing universal testing of pregnant women:

Counselor: Agencies should have a training program in place for all new employees, existing employees and volunteers that will be providing CTR services. This program should ensure that all CTR providers receive adequate training, annual training updates, continuing education and adequate supervision to implement CTR services and the rapid HIV test if appropriate. It should also ensure that CTR providers are skilled and competent in the provision of services by using observed practice of CTR sessions with feedback to counselors and of rapid HIV test procedures if needed. Agencies should have in place a mechanism to assure that all testing protocols are followed as written. QA activities can include observation of sessions as well as role-play demonstration of skills. The review should focus on ensuring that the protocol is delivered with consistency and responsiveness to expressed client needs and should assist counselors with intervention delivery and skill development. For CBOs using the rapid HIV test control kits, available from OraSure Technologies, should be used to ensure reliability and validity of the test

process and materials. CDC also offers the *Model Performance Evaluation Program* to ensure accurate testing as a basis for development of prevention and intervention strategies. (For QA activities related to rapid HIV testing, please review the Procedural Guidance for Rapid Testing in Non-clinical Settings)

Selected intervention record reviews should focus on assuring that consent was obtained or documented for all participants and all process and outcome measures are completed as required.

Client: Clients' satisfaction with the services and their comfort should be assessed periodically. Process monitoring systems should also track the number referrals made and completed as well as response to the service.

Facility: Supervisors should periodically review the testing facility to ensure that a private and confidential setting is available for testing, and that the waiting time for a test does not create a barrier to testing. Feedback should be solicited medical to ensure that test providers are integrated appropriately into the clinic setting.

MONITORING AND EVALUATION

Evaluation and monitoring of recruitment activities include the following:

- Collect and report client-level data.
- Collect and report standardized process and outcome monitoring data consistent with CDC requirements.
- Use of the CDC developed PEMS (Program Evaluation Monitoring System) to report date electronically. Organizations may use, under certain circumstances, a local system provided it meets required system specifications.
- Collect and report data consistent with CDC's requirements to ensure data quality and security and client confidentiality.
- Collaborate with CDC in assessing the impact of HIV prevention activities by participating in special projects upon request.

KEY ARTICLES AND RESOURCES

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[2]Guay LA, Musoke P, Fleming T, et al. Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: HIVNET 012 randomised trial. Lancet 1999;354:795-802.

[3]Wade NA, Birkhead GS, Warren BL et al. Abbreviated regimen of zidovudine prophylaxis and perinatal transmission of the human immunodeficiency virus. N Engl J Med 1998;339:1409-

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[4]Connor EM, Sperling RS, Gelber R, et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. N Engl J Med 1994; 331:1173-1180. Centers for Disease Control and Prevention (CDC). Revised recommendations for HIV screening of pregnant women. MMWR 2001; 50 (RR 19: 50-86).

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[6]Stringer EM, Stringer JS, Cliver SP, Goldenberg RL, Goepfert AR. Evaluation of a new testing policy for human immunodeficiency virus to improve screening rates. Obstetrics & Gynecology 2001;98(6):1104-1108.

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Cohen M et al., Rapid point-of-care testing for HIV-1 in labor and delivery: Chicago, 2002. In preparation for MMWR.

ACOG: http://www.acog.org/

AIDS Education and Training Centers: http://hab.hrsa.gov/educating.htm

CDC perinatal HIV prevention website: http://www.cdc.gov/hiv/projects/perinatal

PRAMS website: http://www.cdc.gov/nccdphp/drh/srv_prams.htm

Rapid testing: http://www.cdc.gov/hiv/rapid_testing/

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